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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Circulatory System Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name Of Committee: Circulatory System Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on December 7, 1998, 8 a.m. to 5 p.m.

Location: Holiday Inn, Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: John E. Stuhlmuller, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8243, ext. 157, or FDA Advisory Committee Information Line, 1-800-74 1-8 138 (301-443-0572 in the Washington, DC area), code 12625. Please call the Information Line for up-to-date information on this meeting.

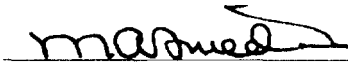
Agenda: The committee will discuss and make recommendations on clinical trial requirements for future approval of coronary stents. An outline of the types of issues to be discussed by the committee can be found on the FDA website at “ <http://www.fda.gov/cdrh/upadvmtg.html>”. Single copies of this outline are also available to the public by contacting the Division of Small

Manufacturers Assistance, Center for Devices and Radiological] Health, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. 1-800-638-2041 or 301-443-6597.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by November 30, 1998. Oral presentations from the public will be scheduled between approximately 8 a.m. and 8:30 a.m., on December 7, 1998. Near the end of committee deliberations, a 30-minute open public hearing will be conducted for interested persons to address issues specific to the topics before the committee. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 30, 1998, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.
2).

Dated: November 12, 1998



Michael A. Friedman
Deputy Commissioner for
Operations

[FR Dec. 98-???? Filed (?) 12-98: 8:45am]

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